

REMARKS

The above amendments have been made in order to remove subject matter from dependent claims which had already been provisoed out of the independent claims from which they depend. Applicants noticed this oversight when reviewing the Office Action, particularly the Examiner's comment in Paragraph 5 (Page 3) that

"...[f]urthermore, claim 9 recites calcium carbonate as a solubilizing agent, therefore, calcium carbonate is inherently permitted."

Thus "calcium carbonate" has been deleted from claim 9, and from claims 14 and 21 in which it also occurred.

' Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page(s) is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE"**.

As a preliminary matter, please note the Notice of Appeal which has been submitted herewith.

Claims 1-29 stand rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner contended that the negative limitations added in the amendment of 5-21-01 depart from the originally filed specification as the originally filed specification recites inclusion, as solubilizing agents, of the agents excluded.

The rejection is traversed on the basis that the agents provisoed out of the claims by Applicants' 5-21-01 amendment emphatically do not constitute new matter. The Examiner appears to be taking the position that Applicants, by means of their provisos (termed "negative limitations" by the Examiner), have tried to characterize their invention in a way that is not supported by the description in their specification. Applicants are not using unsupported description to characterize anything, however; Rather, Applicants are re-defining the metes and bounds of their invention by eliminating, as solubilizing agents, compounds which accidentally overlap with prior art, thereby claiming less than they originally claimed. Applicants have a perfect right to re-define their invention by making such provisos. See In re Johnson and Farnham, 194 USPQ 187 (CCPA 1977). In Johnson, Applicants had entered a proviso into their claims to delete species that were lost in an interference. The issue was whether Applicants' amended claims were entitled to the filing date of an earlier parent application. The Board held that Applicants were not so entitled:

The examiner and the board were of the view that the claims are not entitled to the 1963 filing date because the presently claimed subject matter is not "described" in the 1963 application as required by the first paragraph of 35 USC 112.¹⁴ As explained by the board:

"...we are constrained to conclude that the present claims are not entitled to the filing date of appellants' parent case Serial No. 295,519. The claims at issue contain provisos that E and E' may not both include a divalent sulfone group and may not both include a divalent carbonyl group linking two aromatic nuclei. The artificial subgenus thus created in the claims is not described in the parent case and would be new matter if introduced into the parent case. It is thus equally "new matter," i.e., matter new to the present application for which no antecedent basis exists in the parent case. Consequently, appellants are not entitled to rely on the filing date of their parent case to support a new subgenus for which no basis exists in the parent case. The reason why appellants now limit their claims to exclude those species eliminated by the provisos, i.e., loss in an interference, is manifestly immaterial."
[194 USPQ at pages 192 to 193]

The Court disagreed with (and reversed) the Board of Appeals, ruling that:

While the board found that "no antecedent basis exists in the parent case" for the "limited genus" in claim 1, we see more than ample basis for claims of such scope. The 1963 disclosure is clearly directed to polymers of the type claimed.....Two of the many choices for E and E' precursor compounds are deleted from the protection sought, because appellant is *claiming less* than the full scope of his disclosure. But, as said in *In re Wertheim*, 541 F.2d, 263, 191 USPQ 90, 97 (CCPA 1976):

"Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. It is for the inventor to decide what *bounds* of protection he will seek."
[194 USPQ at pages 195 to 196]

The description from Wertheim fits the exact situation in the instant rejection, making it clear that Applicants' provisos do not run afoul of §112. Applicants have not re-written their claims based on unsupported characterization. Applicants have simply re-drawn their claim boundaries to conclusively and unequivocally avoid any accidental overlap with prior art, and Applicants, per Johnson and Wertheim (see particularly the citation to In re Wertheim in Johnson), are clearly allowed to do so. Thus the Examiner is respectfully urged to reconsider and withdraw the rejection.

In respect of Paragraph 5, it is respectfully requested that the rejection be withdrawn, particularly in consideration of Applicants' amendments to claims 9, 14, and 21. That is, reference to calcium carbonate has now been eliminated. The Examiner's comment that the claims say what the invention is not, rather than what it is, is traversed and/or not understood. Applicants have recited their invention in positive language, albeit some claims employ functional language. Applicants are unaware of any legal proscription against the use of functional language. It appears the rejection may be directed against Applicants' use of provisos to exclude certain substances from the claims. If this is indeed the case, the Examiner is asked to reconsider. The use of provisos is a frequently employed drafting tool used to ensure novelty, particularly when accidental anticipations show up in the prior art. It is not seen that there is any legal obstacle to using proviso language which, by its nature, is usually negative.

Claims 1-29 continue to be rejected under 35 USC 103(a) over Bacopoulos, US 5,130,338. The Examiner stated that

'338 teaches sertraline compositions that appear to be the same as the instant claims. For solubilizing agents, see column 2, line 51-column 4, line 8. Products of identical chemical composition can not have mutually exclusive properties. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. It is unclear whether '338 contemplates immediate or controlled release dosage forms, however it would have been obvious to one skilled in the art at the time of the invention to adjust the amounts of excipients to provide a particular release rate. [Page 3, Paragraph 7 of the Office Action]

From Paragraph 8 of the Office Action, it appears the rejection is based in part on the fact that Applicants' previous amendments are considered new matter. The Examiner also contended that Applicants' are wrong in their contention that the rejection is based on hindsight reasoning, noting, *inter alia*, that

"...so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned from the applicant's disclosure, such a reconstruction is proper."

In Paragraph 9 of the Office Action, the Examiner has combined several secondary references with '338 to teach equivalence between the sesame oil, peanut oil, and sodium lauryl sulfate on one hand and other solubilizing agents not specifically disclosed in '338.

In any case, the starting point for an analysis of obviousness is Graham v. John Deere Co., 383 US 1, 148 USPQ 459, (1966), which mandates determining, **at the time the invention was made**, the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. With respect to the instant claims, the criteria which heavily augurs in favor of patentability are (a) the scope and content of the prior art and (b) the differences between the prior art and the claims at issue. With respect to these two criteria, and at the time the invention was made:

1. the prior art was silent about the tendency of sertraline salts to gel and/or exhibit reduced solubility in chloride-containing use environments (see page 1, lines 20 et seq of Applicants' specification).
2. the prior art was silent about the identity of chemical agents which would improve the solubility of sertraline salts in chloride-containing use environments.

Thus the prior art says nothing about the problem Applicants have solved, and says nothing about the solution. Applicants acknowledge that Bacopoulos ('338) discloses a few compounds, for purposes other than solubilization, which were within the scope of their claims as solubilizers. These compounds have been provisoed out and, as discussed above, such proviso is proper. Because of the provisos, anticipation under 35 USC 102 is not an issue. Only obviousness remains to be resolved.

The Examiner states that his hindsight reconstruction is proper, alleging that it does not involve knowledge gleaned from the applicant's disclosure. Applicants do not see how the Examiner could possibly find the invention obvious without the use of hindsight, however. First, Applicants' claims are directed to improving the solubility of sertraline in chloride ion-containing use environments, not simply the improvement of solubility generally, for example in pure aqueous environments or other types of environments comprising different solvents. '338 never mentions anything about solubilizing sertraline, however. The use of solubilizers which improve sertraline solubility in chloride-containing environments cannot be obvious if the prior art says nothing about the existence of any particular problem in respect of sertraline's solubility in an aqueous chloride-containing environment. Viewed in alternative wording, why would one of ordinary skill in the art consider it obvious to incorporate a solubility enhancing agent in a sertraline-containing composition if there was no known reason or impetus, founded in the prior art, for doing so in the first place? The Examiner accordingly must, therefore, have implicitly attributed the phenomenon of reduced sertraline solubility in chloride ion-containing environments, which only the inventors teach in their specification, to the prior art. That is the only way

Applicants' invention could be found obvious.

The Examiner seems to have otherwise crystallized the basis for the rejection in a single section of the rejection:

The motivation to use a particular solubilizer is based on the upon the known properties of the solubilizer in a particular dosage form. Furthermore, products of identical chemical compositions can not have mutually exclusive properties. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. [Paragraph 8 of the Office Action, page 4, middle of page]

Paraphrasing and interpreting the above quotation, the Examiner appears to be reasoning that (1) Applicants have excluded certain solubilizers from their claims, but (2) for other solubilizers the Applicants invention is still obvious because one of ordinary skill in the art would know to use a different solubilizer.

The reasoning presented by virtue of the above quotation is believed to be misplaced. None of the materials Applicants provisoed out of their claims are uniquely known as solubilizing agents. Further, none of the excluded compounds is disclosed as a solubilizing agent in '338 but, rather, is disclosed for completely different purposes. The materials provisoed out of Applicants' claims are alginic acid, sodium citrate, calcium carbonate, sesame oil, peanut oil, sodium lauryl sulfate, and a polyethylene glycol having a molecular weight greater than 3350. Alginic acid is disclosed in '338 as a disintegrant. Sodium lauryl sulfate is disclosed as a lubricating agent. Polyethylene glycol is disclosed as a filler. Sesame oil and peanut oil are disclosed as solvents for use in parenteral, presumably non-aqueous, administration systems. Sodium citrate and calcium carbonate are disclosed simply as "excipients". Nothing about solubilizing agents are mentioned in '338. That, again, illustrates the basis for Applicants' position that the rejection must be based on hindsight. There is simply no reason to home in on the foregoing compounds as solubilizing agents when '338 never talks about any reason for doing so, and never discusses solubilizing agents even generally.

The Examiner has cited several references (Harvey, Hefti, Crocker, and Dell Acqua) as showing equivalence between sesame oil, peanut oil, and sodium lauryl sulfate on the one hand, and other solubilizing agents on the other hand. First, given Applicants' provisional filing date of July 1, 1997, Crocker and Hefti are not references in the instant application at all, and Harvey is a reference for novelty only. Whether a particular document does or does not qualify as a document is considered to be a subsidiary point, however, since, even if all of the documents did qualify as references, the rejection would still be misplaced. The point is that the secondary references appear to have been

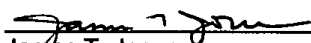
selected because they allegedly teach the equivalence of solubilizing agents they disclose to materials which have been provisoed out of Applicants' claims. But, given the person of ordinary skill, those references would have been selected only in hindsight, because the primary reference ('338) fails to disclose or mention anything relating to solubilizing agents. Viewed alternatively, there is no reason for one of ordinary skill in the art to consider references dealing with solubilization if the solubilization of sertraline had never been flagged in the prior art in the first place. Only Applicants' disclosure does that, and it emphatically cannot be used as a reference against Applicants. W. L. Gore & Associates, Inc. v Garlock, Inc., 220 USPQ 303 (CAFC 1983).

It is accordingly respectfully requested that the rejections under 35 USC 103(a) be withdrawn.

In view of the foregoing comments and amendments, it is respectfully submitted that this application is in condition for allowance. A Notice of Allowance is accordingly respectfully requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

9. A composition as defined in claim 1, wherein said solubilizing agent is selected from aspartic acid, glyceryl monocaprylate, glyceryl monolaurate, calcium acetate, ascorbic acid, citric acid, and glutamic acid[, and calcium carbonate].

14. A composition as defined in claim 10, wherein said solubilizing agent is selected from aspartic acid, glyceryl monocaprylate, glyceryl monolaurate, calcium acetate, ascorbic acid, citric acid, and glutamic acid[, and calcium carbonate].

21. A composition of matter as defined in claim 15, wherein said solubilizing agent is selected from aspartic acid, glyceryl monocaprylate, glyceryl monolaurate, calcium acetate, ascorbic acid, citric acid, and glutamic acid[, and calcium carbonate].